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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/007,093	01/14/98	ANAND	N 1038-765-MIS
		HM12/0717	EXAMINER
			TUNG, M
			ART UNIT
			PAPER NUMBER
		1644	18
		DATE MAILED:	07/17/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/007,093	Applicant(s) Anand, et al.
Examiner Mary B. Tung	Art Unit 1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 1/3/2001 and 4/30/2001

2a)  This action is FINAL.

2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 835 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-11, 27, and 28

is/are pending in the applica

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from considera

5)  Claim(s) \_\_\_\_\_ is/are rejected.

6)  Claim(s) 1-11, 27, and 28 is/are objected to.

7)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirem

8)  Claims \_\_\_\_\_

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). 13

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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**DETAILED ACTION**

1. Claims 1-33 were originally presented.
2. Claims 26 and 29-33 were cancelled in the paper filed 1/14/98, Paper No. 2
3. Non-elected claims 12-25 were cancelled in the paper filed 1/25/99, Paper No. 4.
4. Claims 1-11, 27 and 28 are pending.

The Examiner acknowledges the Applicants comments in the paper filed 4/30/2001, Paper No. 17. The amendment filed 7/3/2000, Paper No. 12, is proper.

***Claim Rejections - 35 U.S.C. § 103***

5. Applicant's arguments filed in the paper filed in Paper No. 12, have been fully considered but they are not persuasive.
6. Claims 1-4, 27 and 28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (US Patent No. 4,950,480) in view of Skea (*Vaccine* 11(10):994-1003, 1993).
7. The Applicants repeated their arguments that there are inherent disadvantages to the biotin-streptavidin system that was used by the '480 patent and that the Applicants employ a recombinant approach to provide the conjugate antibody. This argument stands non-persuasive because one of ordinary skill in the art would have been motivated to make recombinant monoclonal antibodies in order to reduce variability between batches and also to make antibodies in large amounts.
8. Claims 1-4, 27 and 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (US Patent No. 5,194,254) in view of Skea (*Vaccine* 11(10):994-1003, 1993).
9. The Applicants' arguments and Examiner's reply discussed *supra*, are applicable to the instant rejection.
10. The rejection of claims 1-11, 27 and 28 under 35 U.S.C. 102(a) as being unpatentable over Barber (US Patent #4,950,480), in view of Baier et al. (*J. Virol.* 69(4):2357-2365, 1995), is hereby withdrawn in light of the declaration filed under 37 C.F.R. 1.131.
11. The rejection of claims 1-11, 27 and 28 under 35 U.S.C. 102(b) as being unpatentable over Barber (US Patent #5,194,254) in view of Baier et al. (*J. Virol.* 69(4):2357-2365, 1995), is hereby withdrawn in light of the declaration filed under 37 C.F.R. 1.131.

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12. The rejection of claims 1-11, 27 and 28 under 35 U.S.C. § 102(a) as being unpatentable over Baier et al. (*J. Virol.* 69(4):2357-2365, 1995), is hereby withdrawn in light of the declaration filed under 37 C.F.R. 1.131.

#### ***Double Patenting***

13. The rejection of claims 1-11, 27 and 28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 4,950,480, over Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) is hereby withdrawn in light of the declaration filed under 37 C.F.R. 1.131.

14. The rejection of claims 1-11, 27 and 28 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,194,254, over Baier et al. (*J. Virol.* 69(4):2357-2365, 1995) is hereby withdrawn in light of the declaration filed under 37 C.F.R. 1.131.

*The following is a new grounds for rejection:*

#### ***Claim Rejections - 35 U.S.C. § 112***

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

16. Claims 1-11, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

17. There is a lack of antecedent basis in the phrase "monoclonal antibody moiety". The use of the phrase "recombinant monoclonal antibody moiety" would overcome this rejection.

#### ***Conclusion***

18. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

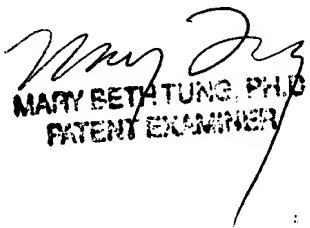
19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm. A

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message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

July 16, 2001  
Mary B. Tung, Ph.D.  
Patent Examiner  
Group 1640

  
MARY BETH TUNG, PH.D.  
PATENT EXAMINER